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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,572	01/29/2001	Eva Kondorosi	200204USOPCT	5065
22850	7590	01/30/2004		
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER COLLINS, CYNTHIA E	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/701,572

Applicant(s)

KONDOROSI ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,8-28 and 30-41 is/are pending in the application.
- 4a) Of the above claim(s) 1,2 and 8-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-28, 30-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 December 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 0104.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 11, 2003 has been entered.

Claims 3-7 and 29 are cancelled.

Claims 1-2, 8-28 and 30-41 are pending.

Claims 1-2 and 8-11 are withdrawn.

Claims 8-12 and 15-18 are currently amended.

Claims 30-41 are newly added.

Claims 12-28 and 30-41 are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, filed December 20, 2002 is attached to the instant Office action.

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Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in France on June 8, 1999. It is noted, however, that a certified copy of French application 98 071774 has not been received in this National Stage application from the International Bureau.

Claim Rejections - 35 USC § 112

Claims 12-28 remain rejected, and claims 30 and 32-41 are rejected, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed March 11, 2003. Claims 12-28 and 30-41

Applicant's arguments filed August 11, 2003, have been fully considered but they are not persuasive.

Applicant argues that the rejection should be withdrawn in view of the amendment of independent claim 12 to recite that the claimed sequences encode a protein which inhibits mitosis and induces endoreplication, and in view of the structural limitation of this claim to (a) SEQ ID NO:1 or a fragment of SEQ ID NO:1 which encodes WD-40 motifs, or (b) sequences which hybridize to the full-length complement of SEQ ID NO:1 under defined stringency conditions (reply page 9).

The rejection is maintained because the currently amended and newly submitted claims continue to be directed to a genus of sequences that are not adequately described. The currently

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amended claims are directed to an isolated nucleic acid comprising any unspecified fragment of SEQ ID NO:1 that encodes a polypeptide that comprises WD-40 repeats and that inhibits mitosis and induces endoreplication. Applicant has not described even one such fragment. Alternatively Applicant has not described the structural features of SEQ ID NO:1 fragments that are correlated with the function of mitosis inhibition and endoreplication induction. Additionally, Applicant has not described a representative number of sequences meeting the structural limitations of claim 12 and additionally encoding a protein at least 70% similar to the CCS52Ms or CCS52Mt proteins, nor the structural features unique to such a genus, as Applicant has described only a single nucleic acid encoding a polypeptide comprising WD-40 repeats that inhibits mitosis and induces endoreplication, the nucleic acid sequence of SEQ ID NO:1. Furthermore, Applicant has not described functions for all sequences that would hybridize to SEQ ID NO:1 under the conditions set forth in newly submitted claim 30, since Applicant has only described a sense sequence (SEQ ID NO:1) that encodes a protein that inhibits mitosis and induces endoreplication, and an antisense sequence (the 1.2 kb SstI-PvuII fragment of SEQ ID NO:1) that inhibits the expression of a protein that inhibits mitosis and induces endoreplication.

Claims 12-28 remain rejected, and claims 30 and 32-41 are rejected, under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid comprising SEQ ID NO:1 that encodes a protein that inhibits mitosis and induces endoreplication, and for an isolated nucleic acid comprising the 1.2 kb SstI-PvuII fragment of SEQ ID NO:1 that inhibits the expression of a protein that inhibits mitosis and induces endoreplication, and for functional sequences that hybridize thereto under the specified

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stringency conditions, does not reasonably provide enablement for other fragments of SEQ ID NO:1, or for sequences encoding other polypeptides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record set forth in the office action mailed March 11, 2003.

Applicant's arguments filed August 11, 2003, have been fully considered but they are not persuasive.

Applicant argues that the rejection should be withdrawn in view of the amendment of independent claim 12 to recite that the claimed sequences encode a protein which inhibits mitosis and induces endoreplication, and in view of the structural limitation of this claim to (a) SEQ ID NO:1 or a fragment of SEQ ID NO:1 which comprises WD-40 motifs, or (b) sequences which hybridize to the full-length complement of SEQ ID NO:1 under defined stringency conditions (reply page 9).

The rejection is maintained because the disclosure of a single nucleic acid sequence of SEQ ID NO:1 encoding a polypeptide that inhibits mitosis and induces endoreplication does not provide guidance with respect to which fragments of SEQ ID NO:1 encode a polypeptide that inhibits mitosis and induces endoreplication. Also, the specification does not provide guidance with respect to how to make sequences that meet the structural and functional limitations of claim 12 and that further encode a protein that is at least 70% similar to the CCS52Ms or CCS52Mt proteins. Additionally, the disclosure of a single nucleic acid sequence comprising the 1.2 kb SstI-PvuII fragment of SEQ ID NO:1 that inhibits the expression of a polypeptide that inhibits mitosis and induces endoreplication does not provide guidance with respect to which

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other fragments of SEQ ID NO:1 inhibit the expression of such a polypeptide. It would require undue experimentation for one skilled in the art to determine which of these sequences would affect mitosis and endoreplication and which would not; as the specification provides no guidance with respect to which nucleotides or amino acids must be retained by sequences that encode a functional polypeptide or that inhibit its expression. Absent such guidance one skilled in the art would have to resort to trial and error screening of the effect of each fragment and sequence variant on mitosis and endoreplication in order to distinguish operative from inoperative embodiments.

Claims 16-17 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of the acronym "CCS52Ms", for the reasons of record set forth in the office action mailed March 11, 2003.

Applicant's arguments filed August 11, 2003, have been fully considered but they are not persuasive.

Applicant argues that the rejection is moot in view of the claim amendments (reply page 9).

The rejection is maintained because the claims continue to recite the acronym "CCS52Ms", which is indefinite absent clarification of what "CCS52Ms" is meant to designate.

Claims 18-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of the acronym "CCS52Mt", as an acronym may be associated with more than one meaning. It is also unclear what sequences are encompassed by a CCS52Mt protein.

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Claims 16, 18 and 29 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of “% similar”, for the reasons of record set forth in the office action mailed March 11, 2003.

Applicant's arguments filed August 11, 2003, have been fully considered but they are not persuasive.

Applicant argues that the rejection is moot in view of the claim amendments (reply page 9).

The rejection is maintained because addition of the limitation “wherein similarity is determined using the blast program” does not clarify what protein characteristic(s) are required to be similar between the claimed protein and the CCS52Ms protein. It is suggested that the claims be amended to recite the characteristic(s) required to be similar, i.e. sequence, in order to overcome the rejection.

Claim Rejections - 35 USC § 102

Claims 12-23 and 26-29 remain rejected under 35 U.S.C. 102(b) as being anticipated by Zhou et al. (Mol. Gen. Genet. Vol. 257, No. 4, pages 387-391, February 1998), for the reasons of record set forth in the office action mailed March 11, 2003.

Applicant's arguments filed August 11, 2003, have been fully considered but they are not persuasive.

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Applicant argues that the rejection is moot in view of the claim amendments that limit independent claim 12 to SEQ ID NO:1 or to sequences which hybridize to the full-length complement of SEQ ID NO:1 under stringent conditions (reply pages 9-10).

The claim amendments do not overcome the rejection because part (a) of independent claim 12 is not limited to a nucleic acid comprising SEQ ID NO:1, but is directed to a nucleic acid comprising SEQ ID NO:1 or any unspecified fragment thereof that encodes a polypeptide comprising WD-40 repeats. Zhou et al. teach a nucleic acid comprising a fragment of SEQ ID NO:1 that encodes a polypeptide comprising WD-40 repeats.

Claim Rejections - 35 USC § 103

Claims 24-25 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Zhou et al. (Mol. Gen. Genet. Vol. 257, No. 4, pages 387-391, February 1998) in view of Applicant's admitted prior art, for the reasons of record set forth in the office action mailed March 11, 2003.

Applicant's arguments filed August 11, 2003, have been fully considered but they are not persuasive.

Applicant argues that the rejection is moot because Zhou et al. is no longer applies to the claims rejected under 35 U.S.C. 102(b) (reply page 10).

As discussed supra, Zhou et al. still applies to the claims rejected under 35 U.S.C. 102(b). Accordingly, the rejection of claims 24-25 under 35 U.S.C. 103(a) is maintained.

Remarks

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794.

The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
January 21, 2004

A handwritten signature in black ink, appearing to read "Amy Nelson", written in a cursive style.

**AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600**